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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,914	09/14/2006	Michael Farrell	3869/041 US	2011

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EXAMINER	
SHOME, ARUNDIPTA	
ART UNIT	PAPER NUMBER
3771	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,914	FARRELL ET AL.	
	Examiner	Art Unit	
	ARUNDIPTA SHOME	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/14/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *17-19,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-19,22 and 23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 September 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-14-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-16, drawn to a method for delivering positive airway pressure and monitoring a patient's cardiovascular condition.

Group 2, claim(s) 17-19 and 22 and 23, drawn to a questionnaire for a patient and a computer for conducting the questionnaire.

The inventions listed as Groups 1 and 2 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: there is no common special technical feature between the two groups, because a method of conducting a questionnaire and a method of delivering positive airway pressure and monitoring a patient have no overlapping features. There is no single general inventive concept between the two groups, and the two groups are independent and distinct.

2. During a telephone conversation with Applicant's representative Michael Rackman on March 10, 2009, a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-16. Affirmation of this election must be made by applicant in replying to this

Office action. Claims 17-19 and 22 and 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

3. The drawings are objected to because in Figure 1, no connection between elements is shown such as control device 12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 3 and 4, the phrase "may be" on line 3 renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US PGPub 2004/0111040).

Regarding Claim 1, Ni discloses method for monitoring the cardiovascular condition of a patient while treating sleep disordered breathing. Ni discloses delivering positive airway pressure at therapeutic levels for treatment of sleep disordered breathing (para. 0050, lines 10-14). Ni also discloses detecting and recording events associated with the treatment of the patient's sleep disordered breathing (para. 0052, lines 1-8).

Ni also discloses storing information concerning the cardiovascular condition of the patient (para. 0056, lines 10-17).

Ni also discloses relating to each other the stored information concerning the cardiovascular condition of the patient and the recorded events associated with the treatment of the patient's sleep disordered breathing (para. 0053 line 1-10 describes how signals associated with sleep disordered breathing such as heart rate are overlapped to detect disordered breathing).

Regarding Claim 2, Ni discloses recording and detecting apneas and hypopneas (para. 0054, line 4).

Regarding Claims 3 and 4, the information on the cardiovascular condition of the patient is stored (para. 0056, lines 10-15) and related to recorded sleep disordered breathing events over time (overlapping signals are used to detect sleep disordered breathing, see para. 0053, lines 1-5).

Regarding Claim 5, Ni discloses a method for treating respiratory disorders and simultaneously monitoring a patient for indications of cardiovascular disease. This method includes delivering positive airway pressure at therapeutic levels for treatment of sleep disordered breathing (para. 0050, lines 10-14).

Ni also discloses detecting and recording, as a function of time (an overlapping set of signals is used, see para. 0053, lines 1-5) events associated with the treatment of the patient's sleep disordered breathing (heart rate, respiration rate, etc. in para. 0052, lines 1-8).

Ni also discloses storing as a function of time the information concerning the cardiovascular condition of the patient (the historical data stored in memory, see para. 0056, lines 10-17).

Ni also discloses relating to each other the information concerning the cardiovascular condition of the patient and the recorded events associated with the treatment of the patient's respiratory disorders (para. 0053, lines 1-5, the information on the cardiovascular condition is

stored with an overlapping set of signals associated with disordered breathing to detect disordered breathing).

Regarding Claim 6, Ni discloses recording and detecting apneas and hypopneas (para. 0054, line 4).

Regarding Claims 7 and 8, the information on the cardiovascular condition of the patient is stored (para. 0056, lines 10-15) and related to recorded sleep disordered breathing events over time (para. 0053, lines 1-5).

Regarding Claims 9, 10, and 11, Ni discloses monitoring hear rate (para. 0052, line 2) continuously together with sleep disordered breathing information on similar time scales (the overlapping signals, para. 0053, lines 1-5). Ni also discloses observing changes in the patient's heart rate associated with changes in sleep disordered breathing to relate to each other the cardiovascular and sleep disordered breathing conditions of the patient (para. 0053, lines 1-5, sleep related signals such as heart rate are used to detect disordered breathing).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US PGPub 2004/0111040).

Regarding Claim 12, Ni discloses performing long-term monitoring of the condition of a patient while treating the patient's sleep disordered breathing (para. 0056, lines 15-17, the

memory circuitry stores historical data and detect disordered breathing over time, which appears to be long term monitoring).

Ni also discloses collecting and storing data concerning the condition of the patient that is obtained from the long term monitoring (the sleep disordered breathing data is stored, see para. 0056, lines 5-10).

Ni does not disclose, in the embodiment shown in Fig. 1 and previously referred to, making the stored data available to a clinician who is treating at least one disease of the patient other than sleep disordered breathing. Ni discloses in another embodiment, shown in Figure 3, making the stored data available to a physician treating at least one disease of the patient other than sleep disordered breathing via a wireless programmer unit 380 (para. 0076, lines 10-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a programmer unit as taught by the second embodiment of Ni to the first embodiment of Ni so that a user can wirelessly access data and control the patient's treatment with ease from a remote location.

Regarding Claim 13, the data is collected and stored while delivering positive airway pressure to the patient at therapeutic levels (para. 0050, lines 10-14).

Regarding Claims 14-16, the data that is stored and made available concerns the cardiovascular condition of the patient (heart rate, para. 0052, lines 1-8) and events associated with the treatment of the patient's sleep disordered breathing (any of the other events in para. 0052).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lee (US PGPub 2005/0065567) teaches respiratory therapy based on a patient's cardiovascular condition.

Schmidt et al. (US Patent 6,186,142) discloses control of respiratory therapy based on blood oxygen content.

Kumar (US patent 6,893,405) teaches analysis of sleep apnea based on measures such as heart rate.

Kadhiresan (US patent 5,974,340) teaches a method for monitoring respiratory function in heart failure patients.

Stahmann (US PGPub 2005/0115561) teaches a patient monitoring system - see Figs. 1C, 67, 72.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is (571)270-5539. The examiner can normally be reached on Monday through Friday 9:00am to 6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Arun Shome/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771